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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,448	03/05/2001	Santu Bandyopadhyay	A34065	2808
21003 7590 02/18/2009 BAKER BOTTS L.L.P. 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112-4498				
EXAMINER EWOLDT, GERALD R				
ART UNIT		PAPER NUMBER		
1644				
NOTIFICATION DATE		DELIVERY MODE		
02/18/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DLNYDOCKET@BAKERBOTTS.COM

Office Action Summary

Application No.

09/800,448

Applicant(s)

BANDYOPADHYAY ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No./Mail Date: _____

DETAILED ACTION

1. Applicant's amendment and remarks filed 11/24/08 are acknowledged.
2. Claims 65-75 are pending.
3. In view of Applicant's amendments the previous objections to claims 65 and 71 have been withdrawn.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 65-75 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

As set forth previously, The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

- B) The method of Claims 65 and 71 comprising:
 - ... c. performing a morphological analysis to demonstrate the presence of dendritic processes in cells of the culture,
- C) The method of Claim 65 comprising:
 - ... d. performing flow cytometric analysis to demonstrate an immunophenotype of dendritic Langerhans type cells in cells of the culture.

Regarding B), Applicant cites paragraphs 54, 30 and 31 (presumably of the pre-grant publication) and Figure 1C.

The cites refer to a specific example (Example 6) of producing human Langerhans cells by a specific method comprising more specific steps than are recited in the claims. Said cite cannot support the more generic claims as are instantly recited.

Regarding C), Applicant cites paragraphs 50 and 51 (again, presumably of the pre-grant publication).

The cites are again from Example 6 wherein cytometric analysis is performed on human Langerhans cells employing specific antibodies. Said cite cannot support the more generic claims as are instantly recited.

A review of the instant amendments shows that Applicant has inserted more of the limitations found only in Example 6 of the specification into parts c. and d. of Claims 65 and 71. A review of the Example reveals, however, that it discloses only a method of generating human dendritic Langerhans cells from human peripheral blood monocytes. Accordingly, this constitutes the introduction of additional new matter into Claim 65. Additionally, the Example is limited to a method employing only autologous platelets in RPMI-1640 medium with or without 2% fetal calf serum. Accordingly, this constitutes the introduction of additional new matter into Claim 71. So while some of these limitations are recited in some of the claims, all of the limitations are recited in none of the claims.

Applicant's arguments, filed 11/24/08, have been fully considered but are not found persuasive. Applicant argues that step (c) is supported by numerous cites including [0054] and [0056].

While the specification discloses generic morphological analysis, it fails to describe what said analysis encompasses. At [0054] the specification discloses that typical dendritic processes were "noticed" when some immature human dendritic cells were cultured under very specific conditions. However, there is no disclosure in the Example of a specific morphological analysis to look for said processes. This is the only disclosure of the "dendritic processes" of the claims and it is insufficient to support the claimed method step.

Applicant argues that Example 6 and [0054] supports step (d).

A review of Example 6 and [0054] shows that the immunophenotyping of the Example was performed only on human monocyte-derived dendritic Langerhans cells and not the generic mammalian dendritic Langerhans cells of Claim 65. Note that the previous rejection of Claim 71 for the recitation of step (d) has been withdrawn.

Applicant argues that under the Examiner's logic Claim 73 should be allowed. Applicant argues that Example 6 consists of only [0050] and [0051].

Claim 73 does not recite all of the limitations of Example 6 or, more specifically [0054], e.g., culture in 2% FCS or serum-free medium. Applicant's argument regarding Example 6

consisting only of [0050] and [0051] is acknowledged, however, the limitations set forth above are still not supported by the specification for the reasons cited.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, Ph.D. can be reached on (571) 272-0878.

9. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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